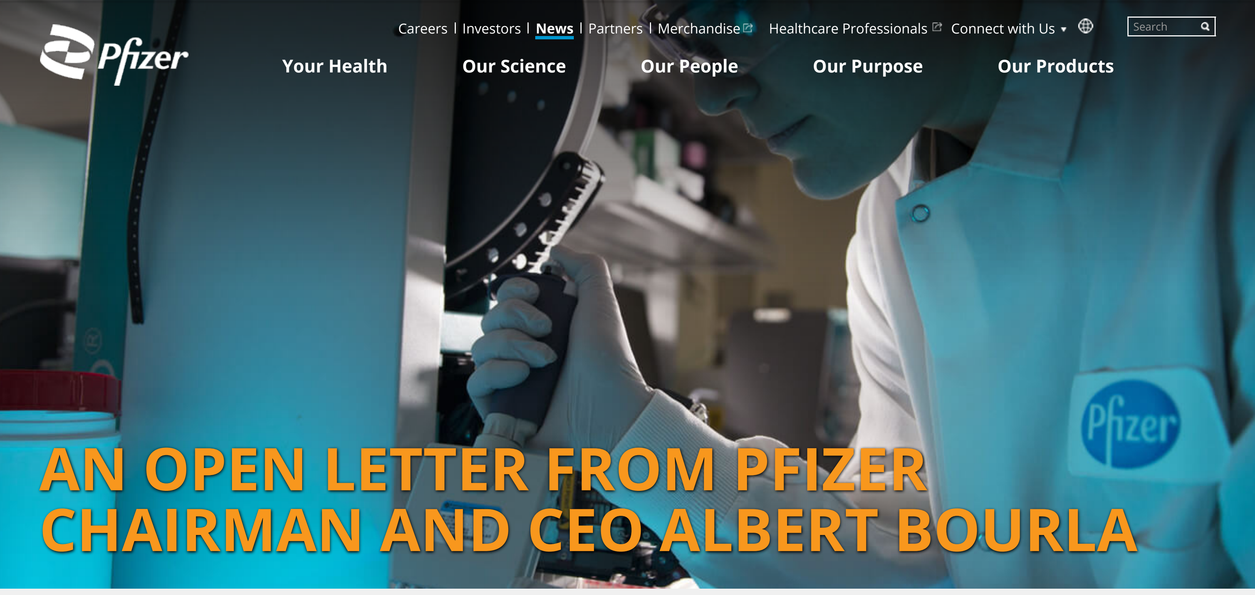

AN OPEN LETTER FROM PFIZER CHAIRMAN AND CEO ALBERT BOURLA

As we get closer to an important data readout from our COVID-19 vaccine program, I wanted to speak directly to the billions of people, millions of businesses and hundreds of governments around the world that are investing their hopes in a safe and effective COVID-19 vaccine to overcome this pandemic. I know there is a great deal of confusion regarding exactly what it will take to ensure its development and approval, and given the critical public health considerations and the importance of transparency, I would like to provide greater clarity around the development timelines for Pfizer's and our partner BioNTech's COVID-19 vaccine.

There are three key areas where, as with all vaccines, we must demonstrate success in order to seek approval for public use. First, the vaccine must be proven effective, meaning it can help prevent COVID-19 disease in at least a majority of vaccinated patients. Second and equally important, the vaccine must be proven safe, with robust safety data generated from thousands of patients. And finally, we must demonstrate that the vaccine can be consistently manufactured at the highest quality standards.

To ensure public trust and clear up a great deal of confusion, I believe it is essential for the public to understand our estimated timelines for each of these three areas.

As I've said before, we are operating at the speed of science. This means we may know whether or not our vaccine is effective by the end of October. To do so, we must accumulate a certain number of COVID-19 cases in our trial to compare the effectiveness of the vaccine in vaccinated individuals to those who received a placebo. Since we must wait for a certain number of cases to occur, this data may come earlier or later based on changes in the infection rates. As Pfizer is blinded to who received the vaccine versus the placebo, a committee of independent scientists will review the complete data and they will inform us if the vaccine is effective or not based on predetermined criteria at key interim analysis points throughout the trial. Pfizer will continue running the trial through its final analysis point even if it is declared effective at an earlier stage. In the spirit of candor, we will share any conclusive readout (positive or negative) with the public as soon as practical, usually a few days after the independent scientists notify us.

A key point that I'd like to make clear is that effectiveness would satisfy only one of the three requirements and, alone, would not be enough for us to apply for approval for public use.

The second requirement is to prove that the vaccine is safe. Our internal standards for vaccine safety and those required by regulators are set high. In the instance of Emergency Use Authorization in the U.S. for a potential COVID-19 vaccine, FDA is requiring that companies provide two months of safety data on half of the trial participants following the final dose of the vaccine. Based on our current trial enrollment and dosing pace, we estimate we will reach this milestone in the third week of November. Safety is, and will remain, our number one priority, and we will continue monitoring and reporting safety data for all trial participants for two years.

And finally, if we achieve a positive efficacy readout and a robust safety profile, the last requirement will be the submission of manufacturing data that demonstrates the quality and consistency of the vaccine that will be produced. Pfizer has been investing at risk since the early days of the pandemic to perfect our manufacturing processes and rapidly build up capacity. We expect to have our manufacturing data ready for submission before the safety milestone is reached.

So let me be clear, assuming positive data, Pfizer will apply for Emergency Authorization Use in the U.S. soon after the safety milestone is achieved in the third week of November. All the data contained in our U.S. application would be reviewed not only by the FDA's own scientists but also by an external panel of independent experts at a publicly held meeting convened by the agency.

The timelines above reflect our best estimates of when these important milestones could be achieved. For 171 years Pfizer has been known for our high-quality standards. Our purpose is to discover breakthroughs that change patients' lives. I cannot think of a breakthrough that would be more meaningful to a greater number of people than an effective and safe COVID-19 vaccine.

In the meantime, I hope you and your loved ones are staying safe and well.

Albert

TAGS:

COVID-19

MORE ON COVID-19

How to stay safe and prevent the spread.

> There are three key areas where, as with all vaccines, we must demonstrate success in order to seek approval for public use.

RELATED HOT TOPICS

SHOT OF A LIFETIME: HOW PFIZER DEVELOPED ITS OWN RAW MATERIALS TO ENSURE A...

SHOT OF A LIFETIME: HOW TWO PFIZER MANUFACTURING PLANTS UPSCALED TO PRODUCE THE...

SHOT OF A LIFETIME: HOW PFIZER IS PARTNERING WITH CMOS TO INCREASE COVID-19...

SHOT OF A LIFETIME: HOW PFIZER AND BIONTECH DEVELOPED AND MANUFACTURED A COVID-...

THE TRUTH ABOUT COVID-19 AND BLACK FUNGUS

CONTINUING TO FOLLOW THE SCIENCE: AN OPEN LETTER FROM PFIZER CHAIRMAN AND CEO...

PARTNERING TO RETHINK VACCINE CONFIDENCE AND RE:SET MENTAL HEALTH AMONG BLACK...

AN OPEN LETTER FROM PFIZER CHAIRMAN AND CEO TO COLLEAGUES

Copyright © 2002-2021 Pfizer Inc. All rights reserved. This information—including product information—is intended only for residents of the United States. The products discussed herein may have different labeling in different countries.